



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,795 | 09/05/2001 | Gunther Berndl | 49727 | 4232 |

26474 7590 09/10/2003
KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 09/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Applicati n No.

09/914,795

Applicant(s)

BERNDL ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Applicant argues that Baert does not teach or suggest each element of the present claims. It is argued that the reference does not teach the instant binders. Furthermore, the applicant argues that Baert only introduces the binders after the melt-extrusion process.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to column 3, lines 33-40 wherein the Baert teaches the use of thermoplastic or thermomelting polymers. These polymers are combined with cyclodextrin and active agents and then melted. Additionally column 4, lines 15-25 is pointed out wherein the process includes mixing the cyclodextrin and active agent, optionally mixing in additives, followed by melting the mixture. Clearly the polymer is added before the melting process to ensure mixing of all ingredients. The crospovidone the applicant speaks of, is utilized for the preparation of the solid dosage form. As seen from the examples, the melt-extrudate is used to make the dosage form.

Secondly, the examiner points out that the claims are rejected under an obviousness rejection; therefore Baert does not have to disclose each and every element of the instant. As clearly stated in the office action dated June 12, 2003, Baert only lack in its teaching of the specific polymers. Thus, Kilmesh et al is relied upon to teach the instant polymer. Kilmesh teaches the method of tableting extrudable composition. Further, Kilmesh teaches the instant melt-extrusion polymers are used conventionally to make the active agent in to a paste form. It is clear these polymers are added to form the melt-extrudable composition. Thus, one would be motivated to combine Baert et al and Kilmesh et al and utilize the instant polymers since Kilmesh

teaches that the instant polymers are conventionally used in the art for melt-extrudable composition. One would expect similar results since Baert utilizes melt-extrusion, which is a polymer extrusion technique that involves utilizing thermomelting polymers.

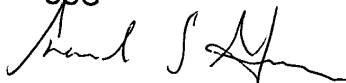
The rejection of Baert in view of Shultz is removed after further reconsideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER

